UNITED STATED DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL No. 1456 Civil Action No. 01-12257-PBS Subcategory No. 03-10643
THIS DOCUMENT RELATES TO:	)	Hon. Patti B. Saris
The City of New York, et al. v. Abbott Laboratories, et al.	)	

SUPPLEMENTAL BRIEF OF UNITED STATES ON THE FEDERAL UPPER LIMIT

The United States respectfully submits this supplemental brief on the Federal Upper Limit ("FUL") program. In the time since the United States filed its Brief of the United States on the Federal Upper Limit in June 2007 (see Dkt #4413) ("2007 FUL Brief"), deposition testimony and documentary evidence has shown that certain statements made in the United States' brief were incomplete, if not inaccurate. The United States submits this brief to correct and clarify its earlier filing. The United States assumes that the Court is familiar with the legal background and general outlines of the FUL program, as explained in governing regulations at 42 C.F.R. §§ 447.331-332 and in the United States' 2007 FUL Brief at pp. 1-3.[1]

[1] In 2005, Congress made changes to the FUL calculation methodology as part of the Deficit Reduction Act of 2005 ("DRA"), Pub. L. 109-171, § 6001, 120 Stat. 4, 54-59 (2006). CMS attempted to implement these changes in a final rule published July 17, 2007. 72 Fed. Reg. 39142. The regulations at 42 C.F.R. §§ 447.331-332 were amended and re-numbered and now appear at 42 C.F.R. §§ 447.512, 447.514. Significant aspects of the July 2007 rule were challenged by the National Association of Chain Drug Stores and the National Community

I. The 2007 FUL Brief

One technical clarification concerns the statement at page 4 of the 2007 FUL Brief that, "For a drug that satisfies the requirements discussed above, CMS sets the FUL for that drug at (1) 150% of the published price for the least costly therapeutic equivalent that can be purchased in quantities of 100 tablets or capsules, plus (2) a reasonable dispensing fee set by each state. See 42 C.F.R. § 447.332(b)." This statement correctly describes the upper limit of the amount to be paid by the state agency for drugs for which a FUL is in effect; however, the FUL published by CMS is determined without regard to a dispensing fee.

The United States' 2007 FUL Brief also stated that the FUL is calculated at 150% of the lowest price published in the national compendia (Blue Book, Red Book, Medi-Span), provided the price is for a product that is widely available in the marketplace. 2007 FUL Brief at 3 n.7 and 4. While this is generally true, it is an incomplete description of the mechanics of the FUL-setting process. As explained in the Declaration of Susan E. Gaston dated June 15, 2009 (Dkt #6144-2), for at least some FULs, CMS has exercised discretion to ensure that the FUL was higher than published WACs of

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Pharmacists Association and subsequently enjoined by a federal court. *National Ass. of Chain Drug Stores v. Leavitt*, Civil Action No. 07-02017-RCL (D.D.C.), Dkt No. 36. Congress then suspended the pertinent DRA provisions. *See* Medicare Improvements for Patients and Providers Act of 2008, Pub. L. 110-275, § 203. The suspension expired September 30, 2009; however, the preliminary injunction remains in effect. Thus, as of the date of this brief, the FUL program has not been changed to conform to the 2005 DRA. The bills pending before Congress on national healthcare reform may resolve the issues giving rise to the preliminary injunction.

available products of at least three manufacturers. This discretion was exercised to ensure beneficiary access to the drugs while still also achieving cost savings for the Medicaid program.[2] Thus, if the FUL calculated from the lowest published price was not higher than the WACs of at least three manufacturers (including the WAC used to calculate the FUL), then CMS might reject the lowest price (treating it, in effect, as an outlier) and instead calculate the FUL based on the next higher price that would yield a FUL that was higher than at least three WACs for available products. *Id*. ¶ 5. This has not been a steadfast rule, however.

The United States' 2007 FUL Brief, with the above corrections and clarifications, provides a generally accurate description of the FUL program.

II. The FULs System and Setting the FUL

The United States is aware that the PowerPoint analysis presented by the defendants' expert Dr. Sumanth Addanki and filed with the Court on July 30, 2009 (Dkt #6332), endeavors to demonstrate that CMS did not follow the approach described above and in Ms. Gaston's testimony. In response, the United States provides further detail concerning the implementation of the FUL program. Attached as Exhibit 1 is the Declaration of Dona M. Coffman dated November 25, 2009 ("Coffman Decl."), which describes the "FULs System" database application that, since 1993, CMS has used to determine FULs. Attached as Exhibit 2 is a Second Declaration of Susan E. Gaston,

[2] *See* 52 Fed. Reg. 28648, 28653 (July 31, 1987) (explaining dual objectives of the FUL program).

dated November 25, 2009 ("Second Gaston Decl."), which responds more directly to Dr. Addanki's PowerPoint slide presentation.[3] This additional information is described below.

Since approximately 1990, CMS has used a database application, referred to as the FULs System, to periodically receive and process data and calculate preliminary FULs.[4] Coffman Decl. ¶ 4. Output from the FULs System contains the pricing information considered by the individual who finally determines the FUL (hereinafter referred to as the "FULs analyst"). *Id*. ¶ 4. The FULs System does not simply download and reproduce all pricing data published by the compendia, and it does not adopt the product grouping system used by any of the compendia, nor is it legally bound to do so. Rather, the System downloads, processes, and groups the data in accordance with criteria designed by CMS to comport with the governing regulation and to further the objectives of the FUL program. *Id*. ¶¶ 8-10, 14-15. The output of this data processing is made available to the FULs analyst, who then manually reviews the print-outs and determines final FULs. *Id* ¶¶ 16-17. The June 15, 2009, Gaston Declaration describes the manual review. The FULs System data processing features, when appropriately understood,

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[3] The United States is separately producing to counsel for the plaintiffs in this case and lead counsel for the defendants, Mr. John Montgomery, two data files with information used by Ms. Gaston, described in the Coffman Declaration at paragraphs 13 and 21.

[4] The FULs System has been upgraded since it was first deployed, but the basics of its processing logic have not changed. The FULs System was generally described by Ms. Gaston in her January 4, 2008, deposition testimony, at pp. 235-259.

show that Dr. Addanki's analysis incorrectly suggests that CMS failed to consistently apply its stated practices in determining FULs.

As explained in greater detail in the Coffman Declaration, the FULs System receives and processes data periodically, based on the request of the FULs analyst. Each downloading and processing event is referred to as a "cycle." Coffman Decl. ¶ 4. When a cycle is run, the FULs System downloads data primarily from two sources: the U.S. Food and Drug Administration's ("FDA's") publication, *Approved Drug Products With Therapeutic Equivalence Evaluations* (commonly known as the Orange Book), and the compendia (First DataBank's Bluebook, the Red Book, and Medi-Span). *Id*. ¶¶ 8-9. In addition, the FULs System receives limited labeler code information from the CMS Medicaid Drug Rebate ("MDR") database, which contains information reported by manufacturers pursuant to the Medicaid Rebate program.[5] *Id*. ¶¶ 11-12. The FULs System organizes the data into product groups appropriate for CMS's purposes, with each group covering drug products having the same ingredient, strength, dosage form, and route of administration. *Id*. ¶ 9. The programming logic that performs the product grouping and assigns products to specific groups is probably different than whatever programming logic is used by the Compendia publishers in establishing their product groups. The Compendia obviously do not share their internal computer code with CMS, and the objectives of the Compendia are not necessarily the same as CMS's objectives.

[5] Average manufacturer price information from the MDR is not used in the FULs System, and the FULs application does not provide such data to the System user.

Once data is received from the Orange Book, the FULs System compares the labeler code data (the first five digits of the NDC number, which identify the company holding the labeler rights) against a data file in the MDR. *Id*. ¶ 11. The MDR file identifies those labelers having effective Rebate Agreements with the Secretary of Health and Human Services, and thus identifies labelers whose products are covered by the Medicaid program. Drug products of labelers who do not have an active Rebate Agreement with the Secretary are excluded from the FULs System output made available to the FULs analyst for consideration in setting an FUL. *Id*. This processing step reflects the determination of CMS that an FUL should not be calculated based on a price for a product that is not eligible for reimbursement under the Medicaid program. *See* 52 Fed. Reg. at 28653 ("The upper limits for drugs contained in this rule pertain only to the Medicaid program.").

During the run of a FULs System cycle, electronic data is received from the Compendia and processed. The precise logic used in the data processing is set forth in the Coffman Declaration and accompanying exhibits. Coffman Decl. ¶ 14. Three features are notable. First, for historic reasons unknown today, the data received from Medi-Span does not include WAC price data. *Id*. ¶ 14 fn.2.[6] Second, if an NDC is designated by Medi-Span as "inactive" or "deleted," or designated by First DataBank as "obsolete," then the FULs System places the record on an "Inactive List" and excludes it

[6] The FULs System does receive WAC data from First DataBank and Red Book.

from the data output considered by the system user in setting FULs.[7] *Id*. ¶ 14. The FUL regulation requires that FULs be based on cost information "for drugs available for sale nationally," 42 C.F.R. § 447.332(a)(1)(ii) (2006), and thus it would not be proper to set FULs on the basis of prices of drugs that are, or soon will be no longer sold nationally. Third, if two out of the three Compendia specify that the NDC is a unit dose form of the drug, the FULs System processing logic excludes the NDC from consideration in setting FULs. *Id*. This reflects a CMS understanding that the unit dose form of a drug is generally not the most commonly used package size of a drug, inasmuch as unit dose forms of a drug are typically used in hospital settings. Second Gaston Decl. ¶ 7.

Data received from the Compendia is processed to update data in existing Product Groups. A series of "matching" steps are performed to assign data of each NDC to a specific Product Group. Coffman Decl. ¶ 15. As can be expected in any system involving large amounts of data submitted from varying sources, this matching process is imperfect due to variations in drug manufacturer nomenclature and other details, and consequently the FULs System places some products into an "unmatched" table until they may be manually reviewed and reassigned to particular Product Groups (a tedious task that is not always performed with perfect regularity). *Id*.; Second Gaston Decl. ¶ 6. A consequence of this data processing, as well as the group assignment processing

[7] In the case of the First DataBank Bluebook data, if the NDC is designated in the Bluebook data as being obsolete, either in the past or within the next six months following the date the data is processed, then the record is placed on the FULs System "Inactive List."

performed in connection with the FDA Orange Book data, is that an NDC that might appear, for example, within a First DataBank "generic code number" (GCN) may not appear in the FULs System Product Group covering the same type of drug. The converse is also true – a specific NDC might appear in a FULs System Product Group but may not appear in a First DataBank GCN group. *See* Second Gaston Decl., Attachments A, H, K, L, M; *see also* Exhibits 3 - 6 attached hereto.

As noted previously, once the FULs System completes its cycle, the output of the data processing is available to the FULs analyst via the on-line system and may be printed out for more in-depth review and analysis.[8] Print-outs before about 2001 have not been located.[9] The FULs analyst manually reviews the FULs System output to ensure that the final FUL is consistent with CMS's program objectives. For prices that are important to the determination of a FUL, the FULs analyst typically contacts the manufacturers to verify that the prices are valid and that the products are widely available in the market. Handwritten notes on the printouts illustrate this practice.

A system upgrade deployed in 1999 gives the FULs analyst limited ability to affect the output of the FULs System. First, the upgrade allows the FULs analyst to

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[8] Before improvements to the FULs System implemented in 1999, printouts of data from the FULs System were more voluminous and required more manual organization as compared to the current system.

[9] A "PC FULS" tool was created in 2001 for record-keeping purposes. This tool preserves a "snapshot" of the data in the FULs System database before the beginning of each new cycle. While this tool is imperfect in certain respects, it provides a reasonably accurate picture of the pricing data available to the FULs analyst when the FUL was set. *See* Coffman Decl. ¶ 18.

annotate the FULs System data by assigning a "T" or "P" exclusion code to an NDC indicate that the product is temporarily or permanently unavailable (typically based on the analyst's communications with the manufacturer as previously noted).[10] Products with these designations still appear on the FULs on-line System and printouts but will not be considered when the FUL is set. Second, the FULs analyst has the ability to re-designate an NDC to a Product Group in the event the analyst learns of an error in the FULs System matching process. With these two limited exceptions, the FULs analyst does not exercise discretion to include or exclude products from the list that appears in the FULs System print-out. Coffman Decl. ¶ 17.

III. Errors in Dr. Addanki's Analysis

CMS has undertaken an analysis of thirteen of the Addanki PowerPoint presentation slides in Exhibit A of the submission filed July 30, 2003.[11] The CMS evaluated the Addanki slides in the order of the GCN numbers used by Dr. Addanki, proceeding chronologically within each GCN group. Analyses have been done for Enalapril, Lorazepam, Clonazepam, Albuterol Sulfate 0.09 MG, and Albuterol Sulfate

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[10] These exclusion codes can be seen in the printouts in the left-hand-most column entitled "Excl CD." *See* Second Gaston Decl., Attachments A, H, K, L, M; and Exhibits 3 - 6 hereto. When an exclusion code is assigned to a product, the FULs System excludes the product from consideration in calculating the preliminary FUL.

[11] In the interests of providing a timely response to the Court, not all of the Addanki slides could be analyzed. Second Gaston Decl. ¶ 4. Given the consistency of the results, however, it is expected that all of Dr. Addanki's slides suffer the same infirmities as described herein and in the Second Gaston Decl. Attachments A - M.

0.083%. The analyses are set forth in Attachments A - M of the accompanying Second Declaration of Susan E. Gaston.

The CMS analysis indicates that the criteria used by Dr. Addanki to select prices to include in his arrays (described in footnotes in Exhibits 3 and 5 of his May 15, 2009, Affidavit (Dkt #57)) are materially different than the criteria used by the CMS FULs System. Dr. Addanki's arrays include (1) products that were designated by the compendia as discontinued or obsolete, (2) products of labelers who did not have active Rebate Agreements with the Secretary and which therefore were not covered by Medicaid, (3) products that are unit dose products, and (4) products that the FULs System could not match to a CMS Product Group. Second Gaston Decl. ¶ 5. The FULs System properly excludes such products from consideration. In every case where there is a FULs System printout to compare against a slide in Dr. Addanki's Exhibit A, Dr. Addanki's slide includes products and prices that are not included in the FULs System printout. *See* Second Gaston Decl., Attachments A, H, K, L, M; *see also* Exhibits 3 - 6 hereto (FULs print-outs and Addanki slides for FULs for Metoprolol Tartrate, Ranitidine Hydrochloride, and Isosorbide Mononitrate).

Dr. Addanki's array slides also frequently include conflicting prices for the same NDC. Where a price is important to a FUL determination and it conflicts with another price for the same NDC, it is CMS's practice to contact the manufacturer to resolve the conflict. Indeed, CMS frequently contacts the manufacturer in the case of any drug

product that is important to a FUL determination, whether or not there is a conflict. It would be inconsistent with the objectives of the FUL program to calculate FULs based on invalid prices or prices of products that are not nationally available. 42 C.F.R. § 447.332(a)(1)(ii) (2006). In sum, the United States submits that the commentary offered by Dr. Addanki regarding CMS's administration of the FUL program is largely unfounded and misleading.

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